ISRCTN24366546 https://doi.org/10.1186/ISRCTN24366546

Mental disorder development in middle childhood: a long-term transdiagnostic prevention study

Submission date
14/11/2025

Recruitment status
Recruiting

Registration date
17/11/2025

Overall study status
Ongoing

Last Edited
25/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Children whose parents have mental illness face a higher risk of developing mental health problems. This study will test whether a three-year, parent-focused, digitally delivered, transdiagnostic prevention program for youth mental health problems results in lower mental health-related functional impairment compared to monitored usual care.

Who can participate?
Families with a 9-year-old child where both biological parents have a lifetime history of mental illness. At least one parent and the child must speak Swedish, be able to attend yearly visits, and have access to the internet and a smartphone or tablet.

What does the study involve?
After consent and baseline assessments, families are randomly allocated 1:1 to either the parent program or monitored usual care. All participants complete in-person assessments at 12, 24 and 36 months after being allocated and short app-based questionnaires every four months for the full study period. Outcome interviews are done by independent assessors who are masked to allocation. The parent program runs for three years and includes yearly 6-week core modules plus yearly 4-week boosters, delivered digitally with guidance. Usual-care families receive no structured program but follow the same assessment protocol and keep all ordinary services.

What are the possible benefits and risks of participating?
Potential benefits include increased awareness of how the child is doing. Parents may gain insight into parenting, family life, and the child’s needs through interviews and questionnaires. Families allocated to the prevention arm receive a structured, digital parent-support program designed to strengthen everyday strategies. Risks are low and relate mainly to time and possible discomfort when discussing sensitive topics. All procedures are non-invasive, and data are handled securely in GDPR-compliant systems. Families in usual care receive information about available support resources.

Where is the study run from?
The study is led by Lund University, in collaboration with the regional child and adolescent mental health services in Skåne, Sweden.

When is the study starting and how long is it expected to run for?
The study is expected to enrol families from November 2025 to December 2028. The last 36-month assessments are expected by December 2031.

Who is funding the study?
1. Forte (Forskningsrådet för hälsa, arbetsliv och välfärd), Sweden.
2. Kavli Trust Programme on Health Research, Sweden.
3. EpiHealth, a joint initiative between Lund and Uppsala universities, Sweden.
4. ALF (Avtal om läkarutbildning och forskning; Agreement on Medical Education and Research), a collaboration between the Swedish government and seven regions to fund physician education and clinical research.

Who is the main contact?
Matti Cervin, PhD, Lund University, Department of Clinical Sciences, Lund, matti.cervin@med.lu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Matti Cervin

ORCID ID
https://orcid.org/0000-0003-1188-8706

Contact details
Lovisastigen 11
Lund
Sweden
222 41
+46737199700
matti.cervin@med.lu.se

Additional identifiers

Forte grant number
2022-00175

Kavli Trust Programme on Health Research grant number
938 503 583

EpiHealth grant number
158837

ALF
PS2537

Study information

Scientific Title
Mental disorder development in middle childhood: a randomized controlled trial of long-term, transdiagnostic prevention

Acronym
IRMA

Study objectives
The principal hypothesis is that a three-year, parent-focused, digitally delivered, transdiagnostic prevention program for youth mental health problems results in lower child mental health impairment at 36 months post-randomization compared to monitored usual care among children at high risk of developing mental disorders.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/10/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2025-05029-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Health services research, Prevention

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of mental health-related impairment in children with high risk of developing mental disorders.

Interventions
This is a single-centre, two-arm, parallel-assignment, superiority RCT with 1:1 allocation to transdiagnostic mental-health prevention or monitored usual care, with masked outcome assessors.

Intervention arm: A three-year, parent-focused, digitally delivered, transdiagnostic prevention program for youth mental health problems with yearly 6-week core modules plus 4-week boosters. During active phases, parents get weekly personalized support from trained interventionists by phone or text messages. In core modules, a midway call occurs in week 3 and a wrap-up call after week 6 to plan maintenance. Each core module starts with a short onboarding meeting to set goals and consists of six weekly chapters that include a brief reading and a practical exercise. The yearly booster modules reactivate core themes. The key components of the program include strengthening the parent–child relationship, building on parental strengths, using praise and constructive conflict strategies, supporting co-regulation of difficult emotions, and establishing family routines, with later years expanding the focus to school and peers, identity, and wider support networks. Standard signposting and crisis contact information are provided when indicated.

Control arm: Monitored usual care, where families use community services as they normally would and follow the same assessment schedule as the intervention arm, but receive no structured intervention content. Standard signposting and crisis contact information are provided when indicated.

Eligible families are randomized 1:1 to intervention or control via a centralized web system with concealed allocation and variable block sizes generated by an independent statistician. The outcome measures are administered by outcome assessors masked to allocation.

Health economic evaluations, including the calculation of Incremental Cost-Effectiveness Ratios, will be performed. Health economic evaluations will be based on the following measures: (a) healthcare and societal resource use for children and caregivers, (b) quality of life in children, and (c) minutes spent on the intervention. The details will be specified in a separate Health Economic Analysis Plan.

Intervention Type
Behavioural

Primary outcome(s)
Child mental health-related functional impairment measured using the interview version of the Uppsala Functional Impairment in Daily life (UFID) at 36 months post-randomization

Key secondary outcome(s))
1. Child mental health-related functional impairment measured using the interview version of the UFID at 12 and 24 months post-randomization
2. Presence of any child mental disorder, any DSM-5 diagnostic category (anxiety disorders, depressive disorders, obsessive-compulsive and related disorders, trauma- and stressor-related disorders, eating disorders, externalizing disorders, and neurodevelopmental disorders), and count of mental disorders, measured using the DIAMOND-KID interview at 12, 24, and 36 months post-randomization
3. Overall child psychosocial functioning measured using the Children’s Global Assessment Scale (CGAS) at 12, 24, and 36 months post-randomization
4. Overall severity of child mental health problems measured using the Clinical Global

Impressions-Severity (CGI-S) scale at 12, 24, and 36 months post-randomization
5. Child anxiety and depression symptoms measured using the child-reported 30-item version of the Revised Child Anxiety and Depression Scale (RCADS-30) at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
6. Child anxiety and depression symptoms measured using the parent-reported 30-item version of the RCADS-30 at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
7. Child externalizing symptoms measured using the parent-rated Conduct Problems Scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
8. Child irritability measured using the child-reported Inventory of Depression and Anxiety Symptoms (IDAS-II) Irritability scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
9. Child irritability measured using the parent-reported IDAS-II Irritability scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
10. Child neurodevelopmental symptoms measured using the Concentrate and Stay Still and Communication scales of the parent-reported Extended Strengths and Weaknesses Assessment of Normal Behavior – General Instrument at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
11. Child emotional resilience measured using the child-reported Behavioral, Emotional, and Social Skills Inventory (BESSI) at 12, 24, and 36 months
12. Child emotional resilience measured using the parent-reported BESSI at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
13. Child loneliness measured using the child-reported UCLA 3-item Loneliness Scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
14. Child mental health-related functional impairment measured using the child-reported UFID at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
15. Child mental health-related functional impairment measured using the parent-reported UFID at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
16. Family functioning measured using the child-reported Family Assessment Device general functioning scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
17. Family functioning measured using the parent-reported Family Assessment Device general functioning scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
18. Parental empowerment measured using the parent-reported Family Empowerment Scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
19. Parental aversive behaviors measured using the parent-reported Parental Abuse Scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
20. Parental aversive behaviors measured using the child-reported Parental Abuse Scale at 12, 24, and 36 months
21. Parent–child relationship measured using the parent-reported Parenting to Reduce Child Anxiety and Depression Scale (PaRCADS) parent–child relationship subscale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
22. Parent involvement in the child's life measured using the parent-reported PaRCADS parent involvement subscale at 12, 24, and 36 months
23. Parent emotional support measured using the parent-reported PaRCADS dealing with negative emotions subscale at 12, 24, and 36 months
24. Family social support measured using the child-reported Multidimensional Scale of Perceived Social Support family subscale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
25. Child self-esteem measured using the child-reported 3-item Rosenberg Self-Esteem scale at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
26. Child quality of life measured using the child-reported Child Health Utility-9D (CHU9D) at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
27. Parental quality of life measured using the parent-reported EQ5D at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months
28. Healthcare and societal resource use for children and caregivers measured using the parent-reported Treatment Inventory of Costs in Patients with Psychiatric Disorders (TiC-P) at 12, 24,

and 36 months
29. Quality-adjusted life years (QALYs) based on the child-reported Child Health Utility–9D (CHU9D) scores at 4, 8, 12, 16, 20, 24, 28, 32, and 36 months.
30. Minutes spent on the intervention reported by interventionists at 6, 12, 18, 24, 30, and 36 months

Completion date
31/12/2031

Eligibility

Key inclusion criteria
1. Child age: Child must have turned or turn 9 during the current calendar year (assessed by year of birth).
2. Two biological parents with a lifetime history of mental illness: Parental mental illness is assessed in two steps. At screening, a semi-structured interview explores the following areas: (i) prior psychiatric or mental health treatment, (ii) mental disorder diagnosis by a health professional, (iii) inpatient psychiatric care, (iv) psychiatric medication or psychological treatment for a mental disorder, and (v) mental health-related sick leave. If only one parent is available, this parent provides information about the other parent. At baseline, each participating biological parent is invited to a diagnostic interview. Lifetime parental mental disorder status is based on the best available information from both steps.
3. Language ability: Child and at least one biological parent must be able to read, write, and communicate in Swedish (per parent report).
4. Assessment participation: Child and at least one biological parent must be able to attend yearly in-person assessments at the research unit (per parent report).
5. Digital access: Family must have access to the internet and a smartphone or touchscreen tablet (per parent report).
6. Willingness to participate in parent-focused prevention: At least one biological parent must express willingness to engage in a long-term digital prevention program (per parent report after parental mental disorder status has been determined).

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
9 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Safety or welfare risks: Any child- or parent-related condition that would make participation unsafe or unethical, such as acute suicidality, uncontrolled neurological illness, confirmed ongoing abuse investigations, or current need for inpatient psychiatric/medical care.
2. Practical barriers to study adherence: Circumstances likely to disrupt required visits, follow-ups, or digital access, such as expected relocation outside the region, unresolved custody disputes, lack of reliable internet/smartphone access, or simultaneous participation in another long-term psychosocial intervention trial.
3. Ability to use the program: Limitations that prevent meaningful engagement with the digital intervention, such as intellectual disability or major sensory impairment.

Date of first enrolment
24/11/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Sweden

Study participating centre
Forskningsmottagning barn- och ungdomspsykiatri Lund
Lovisastigen 11
Lund
Sweden
221 85

Sponsor information

Organisation
Lund University

ROR
https://ror.org/012a77v79

Funder(s)

Funder type

Not defined

Funder Name
Kavlifondet

Alternative Name(s)
The Kavli Trust, Kavli Trust, O. Kavli og Knut Kavlis Almennyttige Fond

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Norway

Funder Name
Forskningsrådet för hälsa, arbetsliv och välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Avtal om läkarutbildning och forskning (ALF)

Funder Name
EpiHealth

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information caregivers	30/10/2025	17/11/2025	No	Yes
Participant information sheet	Participant information children	30/10/2025	17/11/2025	No	Yes
Protocol (other)		30/06/2025	17/11/2025	No	No
Statistical Analysis Plan		11/11/2025	17/11/2025	No	No